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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,482	11/19/2003	Naveen Arora	2761-0169P	3751

2292 7590 11/17/2008

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

NOTIFICATION DATE	DELIVERY MODE
11/17/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/715,482	ARORA ET AL.	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3-8,36 and 37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3-8,36 and 37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 November 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

FINAL ACTION

1. This action is in response to Applicant's amendment and remarks filed August 1, 2008. Claims 1 and 6 have been amended. Claims 2, 9-35 and 38 have been canceled. Claims 1, 3-8 and 36-37 are under examination.

Rejections Withdrawn

2. In view of Applicant's amendment and remarks the following rejections have been withdrawn:

(a) rejection of claims 1-3-8, 21 and 35-38 under 35 U.S.C. 112 first paragraph, pages 3-5, paragraph 3.

(b) rejection of claims 1-3-8, 21 and 35-38 under 35 U.S.C. 112 second paragraph, pages 15-16, paragraph 7.

Rejections Maintained

3. The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(a) as anticipated by Bijli et al *(Clin. Exp. Allergy, January 2003)* is maintained for the reasons set forth on pages 5-8 paragraph 4 of the Final Office Action.

The rejection is reiterated below:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* (page 65). Bijli et al teach a protein that is stable at room temperature (see Abstract). Bijli et al teach a 67kDa protein binds IgE (page 68). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner", "is devoid of any carbohydrate moiety", "wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Bijli et al, 2003 discloses a 67 kDa protein that is identified in an SDS-PAGE gel solely by molecular weight. Applicant urges that the one-dimensional SDS-PAGE gel is well known in the art to provide separation solely by molecular weight. Applicant urges that the Declaration of Naveen Arora that attests to the differences between the protein of the present invention and that disclosed by the cited references.

Applicant urges that the claim limitations "inhibits proteolytic cleavage of protective antigen (PA) of *Bacillus anthracis* in a dose dependent manner" and "binds to IgE" and "resistant to trypsin" would require that the protein is in the native form. Applicant urges that the Examiner has provided no evidence that the 67 kDa protein has anthrax anti-toxin activity or would be commercially acceptable for such use.

Applicant urges that a rejection under U.S.C. 102 the molecule disclosed is the same as the claimed molecule.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed August 1, 2008 have been fully considered but they are not persuasive.

Bijli et al, 2003 teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2003 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2003 makes reference to a 67 kDa protein from *Imperata cylindrical* in the Introduction section on page 65 of Bijli et al.

It should be remembered that the term "isolate" is defined as separating something from something else. The prior art teaches that the 67-kDa protein has been extracted by EACA and isolated on SDS gel. See page 68. It should be remembered that the product (e.g. 67-kDa protein) of Bijli et al, 2003 is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be

of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

The declaration of Naveen Arora under 37 CFR 1.132 filed February 6, 2006 is insufficient to overcome the rejection of claims 1, 3-8 and 36-37. There is no evidence in Bijli et al, 2003 that suggests that the amino-terminus of the disclosed 67 kDa protein is blocked.

To address Applicant's comments regarding anthrax anti-toxin activity or would be commercially acceptable for such, use it should be noted that a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

To address Applicant's comments regarding a side-by-side comparison, Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art. Since the protein of the prior art and the

claimed protein are the same they would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2003 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

4. The rejection of claims 1, 3-8 and 36-37 under 35 U.S.C. 102(b) as anticipated by Bijli et al *(Journal of Immunological Methods 260 (Feb. 2002, 91-96)* is maintained for the reasons set forth on pages 9-12, paragraph 5 of the Final Office Action.

The rejection is reiterated below:

The rejection was on the grounds that Bijli et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 93, Figures 1 (a)-(c)). Bijli et al teach a protein that is stable at room temperature (page 92). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" "wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that Bijli et al, 2002 discloses a 67 kDa protein that is identified in an SDS-PAGE gel solely by molecular weight. Applicant urges that the one-dimensional SDS-PAGE gel is well known in the art to provide separation solely by

molecular weight. Applicant urges that the Declaration of Naveen Arora that attests to the differences between the protein of the present invention and that disclosed by the cited references.

Applicant urges that the claim limitations "inhibits proteolytic cleavage of protective antigen (PA) of *Bacillus anthracis* in a dose dependent manner" and "binds to IgE" and "resistant to trypsin" would require that the protein is in the native form. Applicant urges that the Examiner has provided no evidence that the 67 kDa protein has anthrax anti-toxin activity or would be commercially acceptable for such use.

Applicant urges that a rejection under U.S.C. 102 the molecule disclosed is the same as the claimed molecule.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed August 1, 2008 have been fully considered but they are not persuasive.

Bijli et al, 2002 teach an isolated 67 kDa protein extract from *Imperata cylindrica* using EACA and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract and Figure 2). Bijli et al, 2002 teach an isolated protein because the protein is analyzed by SDS-PAGE. It is noteworthy to point out that Bijli et al, 2002 makes reference to a 67 kDa protein from *Imperata cylindrical* in the Introduction section on page 65 of Bijli et al.

It should be remembered that the term "isolate" is defined as separating something from something else. The prior art teaches that the 67-kDa protein has been extracted by EACA and isolated on SDS gel. See page 68. It should be remembered

that the product (e.g. 67-kDa protein) of Bijli et al, 2002 is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

The declaration of Naveen Arora under 37 CFR 1.132 filed February 6, 2006 is insufficient to overcome the rejection of claims 1, 3-8 and 36-37. There is no evidence in Bijli et al, 2002 that suggests that the amino-terminus of the disclosed 67 kDa protein is blocked.

To address Applicant's comments regarding anthrax anti-toxin activity or would be commercially acceptable for such, use it should be noted that a recitation of the

intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

To address Applicant's comments regarding a side-by-side comparison, Applicant has not submitted any evidence to point to the differences between the claimed protein and the protein of the prior art. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities as the claimed protein. Bijli et al, 2002 anticipate the claimed invention.

In view of all of the above, this rejection is maintained.

5. The rejection of claims 1, 3-8 and 36-37 and 38 under 35 U.S.C. 102(b) as anticipated by Verma et al *(International Archives of Allergy and Immunology, 2000, 122:251-256)* is maintained for the reasons set forth on pages 12-15, paragraph 6 of the Final Office Action.

The rejection was on the grounds that Verma et al teach a 67kDa protein purified from *Imperata cylindrica* that binds IgE (page 252). Verma et al teach a protein that is stable at room temperature (page 252). Verma et al teach the 67-kDa protein is a cross-reactive allergen (see the Abstract). Verma et al teach that the 67-kDa protein has at least three antigenic determinants (see the Abstract). Claims limitations such as "hydrophobic in nature", "resistant to trypsin", "has no proteolytic activity", "inhibits proteolytic cleavage of protective antigen (PA) of *B. anthracis* in a dose dependent manner" and "is devoid of any carbohydrate moiety", wherein the range of about 25-20 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin" wherein protein in the range of about 15-5 ng completely inhibits the cleavage of the protective antigen of *B. anthracis* by trypsin", "wherein the protein in the range of about 25 ng to 11, 000 ng is effective in inhibiting the anthrax activity" and "wherein the protein in the range of about 50 to 10, 000 ng is effective in inhibiting anthrax activity" would be inherent in the teachings of the prior art.

Since the Office does not have the facilities for examining and comparing applicant's protein with the protein of the prior art, the burden is on the applicant to show a novel or unobvious difference between the claimed product and the product of the prior art (i.e., that the protein of the prior art does not possess the same material structural and functional characteristics of the claimed protein). See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's Arguments

Applicant urges that the isolated protein of Verma et al is different from the claimed isolated protein. Applicant states that Verma et al's protein is different from the presently claimed protein because the claimed protein can be sequenced using Edman degradation where as Verma et al 's protein cannot be sequenced. Verma et al purify their protein to a single band by SDS-PAGE analysis.

Applicant refers to the declaration submitted under 37 CFR. 1.1.32 filed February 6, 2006.

Applicant urges that Verma et al cannot anticipate the claimed invention.

Examiner's Response to Applicant's Arguments

Applicant's arguments filed August 1, 2008 have been fully considered but they are not persuasive.

The declaration of Naveen Arora under 37 CFR 1.132 filed February 6, 2006 is insufficient to overcome the rejection of claims 1, 3-8 and 36-37 based upon Verma et al as set forth in the Final Office action. As previously stated, the Declaration submitted by Naveen Arora merely discusses the differences in extraction and purification of the protein. The declaration concludes that since the protein of the prior art cannot be sequenced then the claimed protein and the protein of the prior art are different. As

stated below, the purification or production of a product does not impart novelty or unobviousness. The declaration has failed to provide evidence that the claimed protein and the protein of the prior art are different.

Verma et al teach an isolated 67 kDa protein extract from *Imperata cylindrica* and a standard SDS-PAGE gel was used to show protein profiles (see the Abstract, page 252 and Figure 4). Verma et al also teach that the 67 kDa protein was purified using various chromatography methods (page 252).

The product (e.g. 67-kDa protein) of Verma et al is the same as the product claimed by the applicant because they appear to possess the same or similar functional characteristics. It should be remembered that the purification or production of a product by a particular process does not impart novelty or unobviousness to a product when the same product is taught by the prior art. This is particularly true when properties of the product are not changed by the process in an unexpected manner. See In re Thorpe, 227 USPO 964 (CAFC 1985); In re Marosi, 218 USPO 289, 29222-293 (CAFC 1983); In re Brown, 173 USPO 685 (CCPA 1972). Even if applicant's product can be shown to be of higher purity than the product of the prior art reference, applicant's needs to show some unexpected and unique utility or property, such as unexpected biologically significant increase in specific activity with which the increased purity, greater stability and/or practicality or freedom from some restrictive element or adverse side effects inherent in the product preparations of the prior art or some other secondary consideration which the additional degree of purity imparts (to which there is a basis in

the specification) to applicant's product in order to overcome the aspect of the product's purity is relied upon.

To address Applicant's arguments regarding the inability of Verma et al's protein to be sequenced, it should be noted that there are no limitations in the claims that require that the protein is sequenced. It should be noted that because the protein's N-terminal was blocked does not mean that the protein of the art and the claimed protein are different. Applicant has not shown any structural differences between the claimed 67-kDa protein and the 67 kDa protein taught by Verma et al. Since the protein of the prior art and the claimed protein are the same they would necessarily possess all of the same biological activities.

Verma et al anticipate the claimed invention.

Status of Claims

7. No claims allowed.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vanessa L. Ford whose telephone number is (571) 272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
November 9, 2008

/Robert B Mondesi/
Supervisory Patent Examiner,
Art Unit 1645